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Kazuhiro Iida

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EXAMINER

RAMDHANIE, BOBBY

ART UNIT

PAPER NUMBER

1797

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/597,742	<b>Applicant(s)</b> IIDA, KAZUHIRO	
	<b>Examiner</b> BOBBY RAMDHANIE	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Allowable Subject Matter***

1. The indicated allowability of Claims 11-18 is withdrawn in view of the US7274016. Rejections based on the cited reference(s) follow.

### ***Response to Amendment***

#### ***Telephonic Communication***

2. On 02/18/2010, The Examiner telephoned Mr. Robert Gingher to request identification of the subject matter recited in Claims 11-18, in the submitted Drawings. Mr. Robert Gingher responded with the following: Claim 11 is represented in Figure 9; Claim 12 is represented in Figure 11; Claims 13-15 are represented in Figures 12-14; Claim 16 is represented in Figure 26; and Claims 17-18 are represented in Figure 15). The Examiner thanks Mr. Gingher for the clarification and identification of the claimed subject matter in the Drawings.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 11 recites the limitation "said sample-solution inlet unit," "said washing-solution inlet unit," and "said eluent-liquid inlet unit"" in Claim 11. There is insufficient antecedent basis for these limitations in the claim.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 12 & 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Yager et al (US5971158).

7. Applicants' claims are toward a device.

8. Regarding Claims 12 & 13, Yager et al discloses the gradient forming device, comprising: A). A forward flow channel in which a first composition solution flows (See Figure 3 Item 11, channel); B). A backward flow channel placed in parallel with said forward flow channel in which a second composition solution flows (See Figure 3 Item 7, channel); C). A first inlet unit which communicates with said forward flow channel and introduces said first composition solution into said forward flow channel (See Figure 3 Item 5 inlet); D). A second inlet unit which communicates with said backward flow channel in the downstream side of said forward flow channel and supplies said second composition solution into said backward flow channel (See Figure 3 Item 1); and E). A barrier which separates said forward and backward flow channels and allows

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permeation at least of a specific component in said first composition solution or said second composition solution through said barrier (See Figure 3 Item 20, fluid barrier).

9. Additional Disclosures Included: Claim 13: Said forward flow channel and said backward flow channel are flow-channel grooves formed on a single substrate (See Figure 12 & Column 17 line 66 to Column 18 line 6).

10. Claims 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Shaw et al (WO96/12540).

11. Applicants' claims are toward a device.

12. Regarding Claims 12-15, Shaw et al discloses the gradient forming device, comprising: A). A forward flow channel in which a first composition solution flows (See Figure 1 Item 1); B). A backward flow channel placed in parallel with said forward flow channel in which a second composition solution flows (See Figure 1 Item 2); C). A first inlet unit which communicates with said forward flow channel and introduces said first composition solution into said forward flow channel (See Figure 1 Item 1 has an inlet unit); D). A second inlet unit which communicates with said backward flow channel in the downstream side of said forward flow channel and supplies said second composition solution into said backward flow channel (See Figure 1 Item 2 has an inlet unit); and E). A barrier which separates said forward and backward flow channels and allows permeation at least of a specific component in said first composition solution or said second composition solution through said barrier (See Figure 1 Item 8; foraminous sheet).

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13. Additional Disclosures Included: Claim 13: Said forward flow channel and said backward flow channel are flow-channel grooves formed on a single substrate (See Figure 1, the flow paths are grooves formed on a single substrate – Item 8); Claim 14: Said barrier has multiple flow channels communicating with said forward flow channel and said backward flow channel (See Figure 1 Item 8 & Page 5 lines 21-29); and Claim 15: Said barrier is made of a membrane allowing permeation at least of said specific component (See Figure 1 Item 8 & Page 5 lines 21-29).

14. Claims 12-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Iida et al; WO2004/051229 (An English Translation of this WIPO document may be found as US7274016). Rejections are based off of the English translation).

15. Applicants' claims are toward a device.

16. Regarding Claims 12, Iida et al discloses the gradient forming device, comprising: A). A forward flow channel in which a first composition solution flows (See Figures 5 (a & b) Item 320; Figure 6, Item 320); B). A backward flow channel placed in parallel with said forward flow channel in which a second composition solution flows (See Figures 5 (a & b) Item 322; Figure 6 Item 322); C). A first inlet unit which communicates with said forward flow channel and introduces said first composition solution into said forward flow channel (See Figure 6 Item 326); D). A second inlet unit which communicates with said backward flow channel in the downstream side of said forward flow channel and supplies said second composition solution into said backward flow channel (See Figure 6 Item 330); and E). A barrier which separates said forward

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and backward flow channels and allows permeation at least of a specific component in said first composition solution or said second composition solution through said barrier (See Figures 5 (a & b); Figure 6 Item 324).

17. Additional Disclosures Included: Claim 13: Said forward flow channel and said backward flow channel are flow-channel grooves formed on a single substrate (See [0112]); Claim 14: Said barrier has multiple flow channels communicating with said forward flow channel and said backward flow channel (See Figure 5 (a & b) Item 324 has multiple flow channels); and Claim 15: Said barrier is made of a membrane allowing permeation at least of said specific component (See [0133]);

### ***Claim Rejections - 35 USC § 103***

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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20. Claims 11-18 are rejected under 35 U.S.C. 103(a) as being obvious over Iida et al; WO2004/051229 (An English Translation of this WIPO document may be found as US7274016). Rejections are based off of the English translation).

21. Applicants' claims are toward devices.

22. Regarding Claims 11-18, Iida et al discloses the separation device, comprising:  
A). A separation unit which separates a particular substance in a sample solution (See Figure 10 Item 704); B). A liquid flow regulation structure (See Figure 10 Item 712, & 726), comprising 1). A first flow channel in which a first liquid flows (See Figure 10, Items 716, 720, 724, can be considered channels/first channel & Items 712 & 726 comprise a first channel with a blocking unit); C). A blocking unit which communicates with said first flow channel and blocks said first liquid from leaving said first flow channel (See Figures for liquid switch); and D). A second flow channel that introduces a second liquid to said blocking wherein said blocking unit regulates the flow of said first liquid from said first flow channel to said second flow channel (See Figures for liquid switch);  
E). An inlet unit for said sample-solution (See Figure 10 Items 714); F). An inlet unit for a washing-solution (See Figure 10 Item 706); and G). An inlet unit for an eluent liquid for said particular substance (See Figure 10 Item 704); wherein said regulation structure communicates with said separation unit via said first flow channel, said sample-solution inlet unit and said washing- solution inlet unit communicate with said first flow channel prior to said regulation structure and said separation unit, and said eluent-liquid inlet unit communicates with said regulation structure via said second flow channel (See Figure 10). Iida et al does not disclose that the said regulation structure communicates with



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said sample-solution inlet unit and said washing-solution inlet unit communicate with said first flow channel between said regulation structure and said separation unit.

23. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the design/structure of the separation device to comprise said sample-solution inlet unit and said washing-solution inlet unit communicate with said first flow channel between said regulation structure and said separation unit, since Iida et al discloses that critical timing of fluid flow can be achieved by suitable adjustment and design of these reservoirs and solution tanks, or channels (See Column 13 lines 47-53) and because it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70.

24. Additional Disclosures Included: Claim 12: A gradient forming device, comprising: A). A forward flow channel in which a first composition solution flows (See Figure 10 Item 716); B). A backward flow channel placed in parallel with said forward flow channel in which a second composition solution flows (See Figure 10 Item 720); C). A first inlet unit which communicates with said forward flow channel and introduces said first composition solution into said forward flow channel (See Figure 10 Item 714); D). A second inlet unit which communicates with said backward flow channel in the downstream side of said forward flow channel and supplies said second composition solution into said backward flow channel (See Figure 10 Item 706); and E). A barrier which separates said forward and backward flow channels and allows permeation at least of a specific component in said first composition solution or said second composition solution through said barrier (See Figure 10 Items 710 & 712); Claim 13:

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Said forward flow channel and said backward flow channel are flow-channel grooves formed on a single substrate (See Column 6 lines 29-57); Claim 14: Said barrier has multiple flow channels communicating with said forward flow channel and said backward flow channel (See Figure 10 Item 712); Claim 15: Said barrier is made of a membrane allowing permeation at least of said specific component (See Figure 10 Item 710); Claim 16: A liquid switch having a blocking unit which is provided in said backward flow channel at downstream side of the region in contact with said barrier and blocks said second composition solution and a trigger flow channel which communicates with said backward flow channel in said blocking unit or the region downstream side thereof and communicates with said forward flow channel in said first inlet unit or the region downstream side thereof and introduces said first composition solution to said blocking unit (See Figure 10 Item 712; liquid switch); Claim 17: A microchip, comprising a substrate, comprising: a separation device formed on said substrate, comprising: a separation unit which separates a particular substance in a sample solution; a liquid flow regulation structure, comprising: a first flow channel in which a first liquid flows, a blocking unit which communicates with said first flow channel and blocks said first liquid from leaving said first flow channel, and a second flow channel that introduces a second liquid to said blocking unit, wherein said blocking unit regulates the flow of said first liquid from said first flow channel to said second flow channel; an inlet unit for said sample solution; an inlet unit for a washing-solution; and an inlet unit for an eluent liquid for said particular substance, and a gradient forming device formed on said substrate, comprising wherein a forward flow channel in which a first composition solution flows; a

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backward flow channel placed in parallel with said forward flow channel in which a second composition solution flows; a first inlet unit which communicates with said forward flow channel and introduces stock solution of said first composition solution into said forward flow channel; a second inlet unit which communicates with said backward flow channel in the downstream side of said forward flow channel and supplies [[the]] stock solution of said second composition solution into said backward flow channel; and a barrier which separates said forward flow channel and said backward flow channel and allows permeation at least of a specific component in said first composition solution or said second composition solution through said barrier, and wherein said gradient forming device communicates with said eluent liquid inlet unit included in said separation device (See Rejections above and Figure 10); and Claim 18: A mass spectrometric system, comprising a separation unit which separates a biological sample according to the molecule size or the property thereof, a pretreatment unit which performs pretreatments including enzyme digestion treatment of the sample separated by said separation unit, a drying unit which dries the pretreated sample, and a mass spectrometric unit which analyzes the dried sample by mass spectrometry, wherein said separation unit includes the microchip according to Claim 17 (See Rejections above & Figure 17; mass spectroscopy system & Column 18 lines 1-38).

***Telephonic Inquiries***

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to BOBBY RAMDHANIE whose telephone number is (571)270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/B. R./

/Walter D. Griffin/

Supervisory Patent Examiner, Art Unit 1797